

PATENT COOPERATION TREATY

CORRECTED VERSION

From the:
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **4 OCT 2007**

FOR FURTHER ACTION
See paragraph 2 below

Applicant's or agent's file reference
758555C

International application No.
PCT/AU2007/001188

International filing date (day/month/year)
20 August 2007

Priority date (day/month/year)
21 August 2006

International Patent Classification (IPC) or both national classification and IPC
Int. Cl.
A61M 1/12 (2006.01) A61B 17/12 (2006.01)

Applicant
SUNSHINE HEART COMPANY PTY LTD et al

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input checked="" type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA
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PO BOX 200, WODEN ACT 2606, AUSTRALIA
E-mail address: pct@ipaaustralia.gov.au
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Date of completion of this opinion

Authorized Officer
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/AU2007/001188

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ The international application in the language in which it was filed
 - ☐ A translation of the international application into, _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account **the rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☐ not paid additional fees
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☐ not complied with for the following reasons:

[See supplemental sheet]

4. Consequently, this opinion has been established in respect of the following parts of the international application:
- ☒ all parts
 - ☐ the parts relating to claims Nos.

**WRITTEN OPINION OF THE
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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-48	YES
	Claims	NO
Inventive step (IS)	Claims 1-9, 11-30, 32-48	YES
	Claims 10, 31	NO
Industrial applicability (IA)	Claims 1-48	YES
	Claims	NO

2. Citations and explanations:

The following documents were cited in the International Search Report:

D1: WO 2005/041783 (SUNSHINE HEART COMPANY PTY LTD)

D2: US 6626821 (KUNG et al.)

D3: US 6616596 (MILBOCKER)

D4: US 4957477 (LUNDBÄCK)

D5: US 6808483 (ORTIZ et al.)

D6: WO 2005/110512 (PPA TECHNOLOGIES AG)

The present application defines a flexible wrap used to hold an inflatable chamber against an arterial vessel, preferably the heart, which has a curved shape when it is laid out on a flat surface.

Novelty (N)

D1 is another of the applicant's own documents and is the basis for the improvement discussed in the current application. It defines a flexible wrap used to hold an inflatable device against an arterial vessel with two slits formed at the centre of the wrap.

D2 discloses a cardiac wrap comprising a material covering applied to the around the left or right ventricles and further includes a series of inflatable elements which are used to provide active assistance.

D3 discloses a heart assist system comprising a series of inflatable tube pairs which wrap around the heart to approximate the myocardium, bound in place using a sheath.

D4 discloses a heart assist device comprising a double walled jacket adapted to enclose at least the ventricular portion of the heart. The space between the two walls may be filled with a fluid which is easily displaceable.

D5 discloses a heart assist device comprising both a passive, such as a mesh or webbing, and active assistance member such as a fluid inflatable member.

D6 discloses an inflatable device used as an epicardial support comprising a double walled membrane whereby the cavity between the two walls can be inflated through the use of a fluid and a pump.

However there is no disclosure in any of these documents of the dome like portion formed in the wrap when it is laid out flat. Therefore the subject matter of these claims is new and meets the requirements of Article 33(2) of the PCT with regard to novelty.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

- There is no definition for the term “intermediate portion” in the description and as such it is difficult to determine the scope of claims 1-4. As the exact definition of the “intermediate portion” is not defined it makes it difficult to compare prior art wraps with the current application especially in the case of claim 1. However from the drawings and from reading the description it would appear that the intermediate portion corresponds to portion 26 as represented in the Figures and this definition was used when contrasting with the prior art found.
- The scope of Claim 31 is not clear because although it is a method claim there are no method steps. It appears to be identical in scope to claim 10.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International Application No.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **BOX V**

Inventive Step (IS)

Although there is no disclosure of the use of a tension lower than would substantially deform the vessel this would be obvious to the person skilled in the art as substantially deforming the vessel would work against improving the function of that vessel using a assist device. As such claims 10 and 31 are not considered inventive in light of D1-D6.

Industrial Applicability (IA)

The invention defined in the claims is considered to meet the requirements of Industrial Applicability under Article 33(4) of the PCT because it can be made by, or used in, industry.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International Application No.

PCT/AU2007/001188

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **BOX IV**

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claims 1-4 define a flexible wrap designed to hold an inflatable chamber or balloon against the outside surface of a curved vessel. It is considered that the intermediate portion comprising three side by side portions whereby the outer portions are longer than the central portion comprises a first special technical feature.
- Claims 5-9 define a flexible wrap designed to hold an inflatable chamber or balloon against the outside surface of a curved vessel. It is considered that the wrap, when positioned flat on a surface, comprising a dome-like portion comprises a second special technical feature.
- Claims 10-48 define a flexible wrap designed to hold an inflatable chamber or balloon against the outside surface of a curved vessel. It is considered that the wrap holding the chamber against the artery at a tension lower than would substantially deform the vessel comprises a third special technical feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

The only feature common to all of the claims is a flexible wrap designed to hold an inflatable chamber against the outside surface of a curved vessel. However this concept is not novel in the light of the PCT application cited in the specification as prior art, WO 2005/041783.

This means that the common feature can not constitute a special technical feature within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art.

Because the common feature does not satisfy the requirement for being a special technical feature it follows that it cannot provide the necessary technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a posteriori*.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2007/001188

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 1/12 (2006.01) **A61B 17/12** (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI - IPC: (A61M 1/-, A61B 17/-, A61F 2/-) and Keywords: (+cardi+, wrap, inflate, flexible) and like terms

Google Patents - Keywords: "heart assist", jacket, flexible

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A, D	WO 2005/041783 A1 (SUNSHINE HEART COMPANY PTY LTD) 12 May 2005 See Page 2 lines 9-26 and Figures	1-9, 11-30, 32-48
X	See Page 3 lines 15-17	10, 31
A	US 6626821 B1 (KUNG et al.) 30 September 2003 See Column 3 lines 33-55	1-9, 11-30, 32-48
X	See Figures	10, 31
A	US 6616596 B1 (MILBOCKER) 9 September 2003 See Abstract and Column 4 lines 29-65 and Column 5 lines 6-9	1-9, 11-30, 32-48
X	See Column 3 lines 12-14	10, 31

☒ Further documents are listed in the continuation of Box C☒ See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"E" earlier application or patent but published on or after the international filing date

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"O" document referring to an oral disclosure, use, exhibition or other means

"&" document member of the same patent family

"P" document published prior to the international filing date but later than the priority date claimed

Date of the actual completion of the international search
27 September 2007

Date of mailing of the international search report

4 OCT 2007

Name and mailing address of the ISA/AU

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INTERNATIONAL SEARCH REPORT

International application No.

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4957477 A (LUNDBÄCK) 18 September 1990 See Abstract and Figures	1-9, 11-30, 32-38
X	See Figures 1-2	10,31
A	US 6808483 B1 (ORTIZ et al.) 26 October 2004 See Abstract, Column 3 lines 10-40 and Figure 1	1-9, 11-30, 32-48
X	See Column 3 line 57- Column 4 line 2	10, 31
A	WO 2005/110512 A1 (PPA TECHNOLOGIES AG) 24 November 2005 See Abstract and Figure 1	1-9, 11-30, 32-48
X	See Figure 1	10, 31

INTERNATIONAL SEARCH REPORT

International application No.

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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
[See supplemental sheet]

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

Supplemental Box

(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claims 1-4 define a flexible wrap designed to hold an inflatable chamber or balloon against the outside surface of a curved vessel. It is considered that the intermediate portion comprising three side by side portions whereby the outer portions are longer than the central portion comprises a first special technical feature.
- Claims 5-9 define a flexible wrap designed to hold an inflatable chamber or balloon against the outside surface of a curved vessel. It is considered that the wrap, when positioned flat on a surface, comprising a dome-like portion comprises a second special technical feature.
- Claims 10-48 define a flexible wrap designed to hold an inflatable chamber or balloon against the outside surface of a curved vessel. It is considered that the wrap holding the chamber against the artery at a tension lower than would substantially deform the vessel comprises a third special technical feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

The only feature common to all of the claims is a flexible wrap designed to hold an inflatable chamber against the outside surface of a curved vessel. However this concept is not novel in the light of the PCT application cited in the specification as prior art, WO 2005/041783.

This means that the common feature can not constitute a special technical feature within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art.

Because the common feature does not satisfy the requirement for being a special technical feature it follows that it cannot provide the necessary technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a posteriori*.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2007/001188

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
WO	2005041783	GB	2423028	US	2007135677		
US	6626821						
US	616596						
US	4957477	AU	73181/87	BR	8702612	CN	87103753
		CS	8703722	DD	256451	DK	252387
		EP	0247015	FI	872251	HU	44181
		IN	168344	JP	62284644	NO	872108
		NZ	220342	PH	26007	PL	265810
		PT	84916	SE	8602335	ZA	8703539
US	6808483	AU	89120/01	EP	1322229	US	2005113632
		WO	0228450				
WO	2005110512	CA	2566805	CN	1976730	EP	1748808
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.							
END OF ANNEX							